



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/531,769

12/14/2005

Konstantin Aleksandrovich Shestibratov

U 015739-4

6030

140

7590

06/10/2009

LADAS & PARRY LLP
26 WEST 61ST STREET
NEW YORK, NY 10023

EXAMINER

IBRAHIM, MEDINA AHMED

ART UNIT

PAPER NUMBER

1638

MAIL DATE

DELIVERY MODE

06/10/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/531,769	Applicant(s) SHESTIBRATOV ET AL.	
	Examiner Medina A. Ibrahim	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-32, 35, 41, 43, 45 and 47-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26-32, 35, 41, 43, 45, and 47-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03/18/09 has been entered.

Claims 26-32, 35, 41, 43, 45, and 47-49 are pending and are examined.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 26-32, 35, 41, 43, 45, and 47-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 26 is indefinite because steps ii) to iv) are overlapping and unclear as to what is encompassed by each step. It is unclear how many times segments are separated from the leaf disks or explants and how many times the explants/leaf discs are inoculated with the agrobacteria and at what stage. For example, step ii) requires separating a segment from each leaf discs of step i), and step iv) also requires "separating a number of explants, into which the disc inoculated with agrobacteria is

Art Unit: 1638

separated”, and then “in each step” which is confusing. Also, what is encompassed in step v) is unclear. Also, there is no correlation between steps i) to v). Therefore, clarification is required to more clearly define the metes and bounds of the claims. Dependent claims 27-32, 35, 41, 43, 45 and 47-49 are included in the rejection because they do not obviate the rejection.

Claims 48-49 are indefinite because “the section length” lacks antecedent basis. It is also unclear if the explant is the original explant or the segmented leaf discs. clarification is required to more clearly define the metes and bounds of the claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 35 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claim requires specific cultivars such as Champly, Oka, Yamaska, L'Acadie, L'Authentique Orleans, Rosalyne, Roseberry, Saint-Pierre, Donna, Enzed, Levin, Enzed Lincoln, Vilanova, Durval, Redcrest, Bountiful, Redgem, Pelican, Primtime, Mohawk, Latestar, and Winoma. However, the specification does not disclose the availability of all of these cultivars and a search of the prior art does not indicate the cultivars are well

Art Unit: 1638

known in the prior art. Therefore, absent the availability of the cultivars, one of ordinary skill would not be able to practice the claimed invention without undue experimentation.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 26-32, 35, 41, 43, 45, and 47-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mathews et al (US 5, 750, 870) in view of Dogov et al (Genetics and Breeding for crop quality and Resistance, pp. 165-172 (1999); Applicant's IDS).

Art Unit: 1638

The claims are drawn to a method of producing a transgenic strawberry plant, comprising treating the tissue of a plant with *Agrobacterium thumefaciens* which comprises at least one vector into whose composition there enters at least one gene of the method in the step of transformation and producing explants comprises the steps of: i) selecting one or more leaf discs; ii) separating a segment from each disk, for access of the agrobacteria; iii) inoculating the leaf disks with the agrobacteria followed by removing excess agrobacteria iv) separating a number of explants, into which the disc inoculated with agrobacteria is separated, followed by separating 2 to 5 explants; in each step after separating an explant, the remaining portion of the disc is preincubated for 1 to 5 days to provide for inoculating the remaining portion with agrobacteria; from the side of the first section v) preparing lots of explants after each step of separating explants, the lots are transferred onto the selection and regeneration media comprising from 1 to 10 mg TDZ, from 0 to 0.3. mg IBA, and from 10 to 100 mg kanamycin; from the prepared lots, explants, with a lowered frequency of necrotic reactions are selected and one or more transgenic plants are formed; said vector contains a genetic material that encodes a protein which contributes to lowering necrosis, enhances resistance to pathogens including PR1, PR2, PR3, PR4, PR5, or a combination thereof, or a genetic material that encodes a thaumatin; said method, wherein the composition of the selection and regeneration medium includes 5 mg/l of TDZ, 0.3mg/l of IBA, and 50 mg/l of kanamycin; and wherein the ration of the section length and the explant surface area is from 0.1 mm/mm² to mm/mm². Dependent claims 32 and 35 list specific species fungal pathogen and specific strawberry cultivars, respectively.

Mathews et al teach a method of producing transgenic strawberry plant via an agrobacterium tumefaciens, the method comprising i) isolated explants from leaf, petiole were cut into 4-6 mm sized sections prior to cocultivation; ii) preparing a binary vector containing a desired gene and a marker gene; and co-cultivating the segmented explants with the Agrobacterium for 1-3 days; followed by a stepwise selection process in media containing increasing concentrations of kanamycin ; the selection and regeneration media contained 0.1 mg/l to 0.2 mg/l of IBA, and 0.1 to 1 mg/l of TDZ; after three weeks, explants with completely bleached/necrotic tissues were discarded while green or partially green tissues were selected and transferred to a fresh shooting medium; Mathews teaches that 95% to 100% of the transgenic shoots successfully rooted on medium containing 60mg/l of kanamycin; well rooted transgenic plants were quickly established in soil with 100% success (See Examples 6-11 and Table 2; columns 23-28).

Mathews et al do not explicitly teach the use of leaf disks as explants. However, Agrobacterium mediated transformation of strawberry using leaf disks as explants is known in the prior art.

Nehra et al (J. Amer. Soc. Hort. Sci 114:1014-1018 (1989)) is cited by Mathews et al above and teach transformation of strawberry and direct shoot regeneration from strawberry leaf discs and efficient regeneration of redcoat strawberry was achieved with a media containing benzyladenine and indoleacetic acid.

Plessis et al is also cited by Mathews and teach efficient transformation of strawberry cultivar Selektta using via agrobacterium using explants of leaf pieces from greenhouse plants; said leaf pieces were inoculated with agrobacterium strain containing GUS or PAT gene under the control of 35 CaMV in a binary vector; shoots were produced from media containing 50 mg/l of kanamycin.

Dogov et al teach transformation of strawberry and other horticultural crops with thaumatin II gene; the method comprising preparing leaf explants from strawberry variety Feyerverk; co-cultivating it with agrobacterium strain in media containing 2.0 mg/l of IAA for 1-2 days; transferring the explants in a regeneration and selection media containing 50 mg/l of kanamycin and 0.3 mg/l of IBA. The cited reference also teaches expression of thaumatin II induces antifungal property and fruit ripening.

It would have been obvious to one of ordinary skill in the art at the time this application was filed to use the agrobacterium mediated transformation of strawberry using leaf disks and to modify that method by incorporating the thaumatin II gene construct taught by Dogov et al, to produce transgenic strawberry plant having resistance to fungal pathogen as result of expressing thaumatin as suggested by Dogov et al. It would also have been obvious to one of ordinary skill in the art to optimize inoculation, selection and regeneration protocols for the transformation of any strawberry cultivar, given that successful agrobacterium mediation transformation of strawberry using leaf discs as explants from different strawberry cultivars are disclosed in the prior art as evidenced by Nehra and Plessis cited by Mathews et al above. It is the knowledge available to one of ordinary skill in the art of the development of effective

Art Unit: 1638

transformation and regeneration protocols of a desired plant depend upon the various factors such as cultivar, type and source of explants, type of agrobacterium strain, hormone balance and incubation conditions. In addition, the steps as recited in claim 26 is confusing and indefinite as discussed in the above 112, 2nd paragraph rejection. Therefore, the claimed invention as a whole was prima facie obvious, absent a clear and convincing evidence to the contrary. Also, claims 48-49 are included in the rejection because of the 112, 2nd rejection above.

Response to Arguments

In the response filed 03/18/09, Applicant does not clearly identify how the claimed invention distinguishes from the prior art.

Remarks

No claim is allowed.

Contact information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (571)272-0797. The examiner can normally be reached on M-TH 8:00 am to 5:30 PM, and every other Friday from 8:00 AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571-272-0975. The fax phone

Art Unit: 1638

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MAI
6/8/2009

/Medina A Ibrahim/
Primary Examiner, Art Unit 1638